## ADMINISTRATIVE INFORMATION

## I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitted By:

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Contact Person: Lori R. Peterson
At address above

B. Device Trade Name: JETStream® Workspace Workstation
Common Name: Image Processing System
Classification Name: Picture Archive and Communication Systems (PACS)

C. Predicate Device(s):

| Manufacturer | Product Name | 510(k) No. |
|---|---|---|
| ADAC Laboratories | Pegasys Ultra™ | K993946 |
| ADAC Laboratories | Predicate JETStream® Workspace | K042880 |

D. Device Description:

JETStream® Workspace is a Windows®-based Nuclear Medicine workstation for the Nuclear Medicine market segment. The computer system will consist of a Hewlett Packard XW4300 workstation or HP Compaq nc6230 Notebook or their equivalents. The comprehensive tools and features provided with this product, will allow the technologist and/or physician to perform image review, processing of source data, post processing, hardcopy production, interpretation, report generation and contains the utilities necessary to support the workflow and data management between those activities. The system will support connectivity aspects necessary to import and export data as required to accomplish daily work scenarios.

E. Intended Use:

JETStream® Workspace is a nuclear medicine image display and processing workstation that provides software applications used to

process, analyze, and display medical images/data. The results obtained may be used as a tool, by a nuclear physician, in determining the diagnosis of patient disease conditions in various organs, tissues, and other anatomical structures. The data processed may be derived from any nuclear medicine gamma camera. The JETStream® Workspace system should only be operated by qualified healthcare professionals trained in the use of nuclear medicine equipment.

F. Technological Comparison:

The Pegasys Ultra™ (K993946), JETStream® Workspace (Predicate – K042880) and the JETStream® Workspace (modified) have similar indications for use and overall function and perform in a similar manner with respect to, display, review and processing applications, data storage, and system utilities.

## II. CONCLUSION

JETStream® Workspace is substantially equivalent to the following predicate devices, Pegasys Ultra™ (K993946) and JETStream® Workspace (Predicate - K042880) based on similar intended use, technological comparison, and system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 1 2006

ADAC Laboratories
% Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Underwriters Laboratories, Inc.
455 East Trimble Road
SAN JOSE CA 95131

Re: K061029
Trade/Device Name: JETStream® Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 13, 2006
Received: April 14, 2006

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K061029

Device Name: JETStream® Workspace

Indications For Use:

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Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061029